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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/598,686

09/08/2006

Michael Gregory Bell

X-17098

8979

25885 7590 07/01/2010

ELI LILLY & COMPANY

PATENT DIVISION

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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT

PAPER NUMBER

1624

NOTIFICATION DATE

DELIVERY MODE

07/01/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/598,686	<b>Applicant(s)</b> BELL ET AL.	
	<b>Examiner</b> Brenda L. Coleman	<b>Art Unit</b> 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-8,10-14,17,21 and 29-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3,6-8,10-13,17,21,29 and 31 is/are allowed.
- 6) ☒ Claim(s) 2,5,14 and 30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

Claims 1-3, 5-8, 10-14, 17, 21 and 29-31 are pending in the application.

This action is in response to applicants' amendment dated April 6, 2010. Claims 1, 2, 5 and 14 have been amended; claims 24-28 have been canceled and claim 31 is newly added.

### *Response to Amendment*

Applicant's arguments filed April 6, 2010 have been fully considered with the following effect:

1. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection labeled paragraph 2) in the last office action, which is hereby **withdrawn**.
2. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection labeled paragraph 3) in the last office action, which is hereby **withdrawn**.
3. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled paragraph 4a), b), c) and d) in the last office action, which are hereby **withdrawn**. With regards to the 35 U.S.C. § 112, second paragraph rejections labeled paragraph 4e) in the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive.
  - e) The applicants' stated that the 23<sup>rd</sup> and 24<sup>th</sup> entries have been deleted.

However, these species have not been deleted but rather species 39<sup>th</sup> and 40<sup>th</sup>.

Claim 14 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

In view of the amendment dated April 6, 2010, the following new grounds of rejection apply:

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 2, 5 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a. Claim 2 recites the limitation "n is 0" in the second line of the claim. There is insufficient antecedent basis for this limitation in the claim.
- b. Claim 5 is vague and indefinite in that it is not known what is meant by "q are independently 0 or 1".
- c. Cardiac protective agents in claim 30 is a relative terms, which renders the claim indefinite. The specific term of claims 30 "cardiac protective agent" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The nature of the composition

consisting of the compounds of formula I and an additional active ingredient, which are cardiac protective agent.

d. Statins in claim 30 is a relative terms, which renders the claim indefinite.

The specific term of claims 30 "statin" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The nature of the composition consisting of the compounds of formula I and an additional active ingredient, which are statin.

e. Leptin regulating agents in claim 30 is a relative terms, which renders the claim indefinite. The specific term of claims 30 "leptin regulating agent" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The nature of the composition consisting of the compounds of formula I and an additional active ingredient, which are leptin regulating agent.

f. Lipid regulating agents in claim 30 is a relative terms, which renders the claim indefinite. The specific term of claims 30 "lipid regulating agent" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The nature of the composition consisting of the compounds of formula I and an additional active ingredient, which are lipid regulating agent.

***Allowable Subject Matter***

5. Claims 1, 3, 6-8, 10-13, 17, 21, 29 and 31 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brenda L. Coleman/  
Primary Examiner, Art Unit 1624